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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,937	10/25/2001	Christopher R. Ralph	1759.17239-FOR	8882
7590	11/25/2003		EXAMINER	
RYAN KROMHOLZ & MANION, S.C. Post Office Box 26618 Milwaukee, WI 53226-0618			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 11/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/001,937	RALPH ET AL.
	Examiner	Art Unit
	Anu Ramana	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 08 September 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-14 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 6 is/are allowed.
- 6) Claim(s) 1-4, 7, 8 and 10-14 is/are rejected.
- 7) Claim(s) 5 and 9 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 October 2001 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lubeck et al. (US 5,100,390).

Regarding claim 1, Lubeck et al. teach a cannula 9 with a solid closed tip 6 having a side opening 6' (col 5, lines 61-68 and col. 6, lines 4-6) to minimize trauma to penetrated tissues (col. 2, lines 58-68 and col. 3, lines 1-2) wherein side opening 6' is sized to receive a catheter or a “tubular expandable structure.”

Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Stark (US 5,456,267).

Stark discloses a tool including a screw or “cannula” 380 with an internal bore 386; the cannula having a surface or threads 384 on a distal end to anchor the cannula in bone and a side port or “circumferential opening” in a side wall (Figure 19, col. 2, lines 22-24 and col. 6, lines 16-18).

With regard to the side port being “adapted to accommodate passage of an expandable structure from within the bore,” it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Racz (US 5,817,074) in view of Allen et al. (US 5,467,786).

Racz discloses a needle or cannula or instrument 12 having a distal opening 14 communicating with an internal bore and a circumferential opening 18. With regard to the side port being "adapted to accommodate passage of an expandable structure from within the bore," it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Allen et al. teach the use of a guide pin 26 to guide an instrument to a desired location during a surgical procedure (col. 4, lines 16-30).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have sized distal opening 14 of the Racz instrument to accommodate a guide pin, as taught by Allen et al., for the purpose of guiding the Racz instrument during a surgical procedure.

Claims 7-8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stark in view of Scholten et al. (US 4,969,888).

Stark does not disclose the use of hollow screw or "cannula" 380 as part of an assembly for treating bone. See discussion for claim 3.

Scholten et al. teach the use of a hollow screw or cannula with an expandable structure or balloon 76 to treat a vertebral body. Scholten et al. also teach that expandable balloon 76 is used to compact bone marrow or "cancellous bone" to create a void which is then filled with a material such as "synthetic bone."

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the Stark hollow screw in combination with an expandable structure, as taught by Scholten et al., for the purpose of treating a vertebral body wherein so doing would amount to mere substitution of one functionally equivalent structure, namely hollow

screw, for another within the same art and the selection of any of these hollow screws would work equally well in the claimed device.

The method steps of claims 10-14 are performed during normal operation of the assembly of the combination of Start and Scholten et al. during treatment of a vertebral body.

*Allowable Subject Matter*

Claims 5 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 6 is allowed.

*Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Arunadha Kanase*  
November 21, 2003



KEVIN SHAVER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700